

Remarks/Arguments:

Applicants wish to thank Examiner Cynthia B. Wilder, Ph.D., for the courteous consideration rendered their undersigned representative during a telephone conference concerning the final action. The substance of the discussion is set forth, below, in the remarks addressing the §103(a) rejection.

Claims 11 and 19, previously presented, are pending.

Claims 1-10, 12-18, and 20-22 are canceled, without prejudice or disclaimer.

Claims 11 and 19 were rejected under 35 USC 103(a) as allegedly being unpatentable based on *Nucleic Acids Research*, 26, 1854-1855, 1998 (Nakahara) in view of US5654142 (Kievits), *Nucleic Acids Research*, 26 (1998), 2150-55 (Leone), and *Methods in Molecular Biology*, 38 (1994), 253-60 (Malek). Reconsideration is requested.

First of all, applicants incorporate herein by reference their remarks traversing the §103(a) rejection set forth in the responses filed May 8 and November 20, 2006.

Secondly, the §103(a) rejection is maintained in the Advisory Action because, *i.a.*, allegedly (Advisory Action, page 4, first paragraph) (*emphasis in original*):

There is nothing in Applicant's claims or in the instant specification that teaches or suggests that a minimum concentration of 3.2 to 4.4 mM of ITP is *critical* to the instant invention.

The aforesaid telephone conference was initiated in order to elucidate the allegation. During the telephone conference, the undersigned asked whether criticality of the ITP "concentration of 3.2 mM to 4.4 mM" was not evidenced by the data represented in application figures 7 and 8, as explained

in the present specification (page 30, first complete paragraph). Applicants understand that the examiner did not find the specification data at issue sufficiently evidenced criticality.

More precisely, applicants understand that the examiner found the 3.2-4.4 mM ITP concentration to be "optimum" and, thus, not "critical." In other words, applicants understand that the examiner maintained the ITP concentration must be "surprising and unexpected" in order to evidence criticality, i.e., patentability over the prior art. With all due respect, the examiner's findings are not sustainable.

The rejection incorrectly equates an "optimum" difference (over the prior art) with a non-patentable difference and, moreover, incorrectly requires a "critical" difference (over the prior art) necessary for patentability. Section 103(a) does not require an invention to an improvement over, or more complex than, the prior art in order to be patentable. *Demaco Corp. v. F. Von Langsdorff Licensing Ltd.*, 7 USPQ2d 1222, 1225 (Fed. Cir. 1988), *cert. denied*, 488 U.S. 956 (1988). "Nothing in the patent statute requires that an invention be superior to the prior art to be patentable." *Ryco Inc. v. Ag-Bag Corp.*, 8 USPQ2d 1323, 1328 (Fed. Cir. 1988). "An invention need not *operate* differently than the prior art to be patentable, but need only *be* different." *Hewlett-Packard Co. v. Bausch & Lomb, Inc.*, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990) (*emphasis in original*). Since the claimed 3.2-4.4 mM ITP concentration is "different" than the prior art, the present claims are "patentable" over the cited prior art. *Hewlett-Packard Co.*, 15 USPQ2d at 1528.

The rejection mistakenly relies on—language taken out of context from—*In re Aller*, 105 USPQ 233, 235 (CCPA 1955). The statement of rejection (Advisory Action, page 4) cites *Aller* in

alleging "it is not inventive to discover the optimum or workable ranges by routine experimentation." Subsequent case law, e.g., *In re Yates*, 211 USPQ 1149, 1151 (CCPA 1981), has cautioned against reliance on *Aller* by focusing on "routine experimentation" being the (alleged) manner by which the optimum range was discovered. *Yates* clarifies that the issue is whether the claimed range—optimum or otherwise—would have been expected in view of the prior art, i.e., not whether the claimed range was discovered as a result of "routine experimentation." Since the rejection has failed to show that the skilled artisan would have expected the claimed 3.2-4.4 mM ITP concentration to be the optimum range (i.e., would have expected the results set forth on page 30 of the specification), the initial burden of establishing a prima facie case of obviousness has not been met. In the context of a rejection for obviousness under §103(a), the "Examiner bears [both] the initial burden . . . of presenting a *prima facie* case of unpatentability" and "the ultimate burden of persuasion on the issue." *In re Oetiker*, 24 USPQ 1443, 1444 and 1447 (Fed. Cir. 1992).

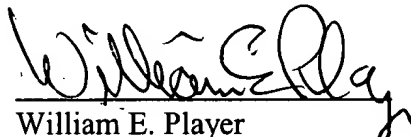
For the foregoing reasons, withdrawal of the rejection under §103(a) appears to be in order.

Favorable action is requested.

Respectfully submitted,

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